

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES  
INTERNATIONAL SRL  
a corporation of Barbados,

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC and  
ANDRX CORPORATION,

Defendants.

C.A. 05-586

**ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants, Andrx Pharmaceuticals, LLC and Andrx Corporation (hereinafter "Andrx"), by its attorneys, answer the Complaint herein as follows:

1. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 1 of the Complaint.
2. Andrx admits the allegations contained in paragraph 2 of the Complaint.
3. Andrx admits the allegations contained in paragraph 3 of the Complaint.
4. Andrx admits the allegations contained in paragraph 4 of the Complaint.
5. Andrx admits the allegations contained in paragraph 5 of the Complaint.
6. Andrx admits that this action arises under the patent laws of the United States of America and specifically under 35 U.S.C. §271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Andrx denies the remaining allegations contained in paragraph 6 of the Complaint.
7. Andrx admits the allegations contained in paragraph 7 of the Complaint.

8. Andrx admits that it manufactures pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District. Andrx denies that it manufactures bulk pharmaceuticals.

9. Andrx repeats the admissions and denials of paragraphs 1-8 above in response to the allegations in paragraph 9 of the Complaint.

10. To the extent that Paragraph 10 of the Complaint states conclusions of law, Andrx states that no response is required. To the extent that Paragraph 10 of the Complaint states allegations of fact, Andrx admits that United States Patent No. 5,529,791 (“the ’791 patent”) was issued on June 25, 1996 to Galephar P.R., Inc., Ltd. (“Galephar”), the assignee of the named inventors, Arthur M. Deboeck and Philippe R. Baudier.

11. Andrx admits the allegations contained in paragraph 11 of the Complaint.

12. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 12 of the Complaint.

13. Andrx denies that there is information sufficient to form a belief as to the allegations contained in paragraph 13 of the Complaint.

14. Andrx admits the allegations contained in paragraph 14 of the Complaint.

15. Andrx admits that on or about June 22, 2005, pursuant to the provisions of 21 U.S.C. § 355(j)(2)(B)(ii), Andrx sent a letter to Biovail, Galephar and to Bank of Nova Scotia notifying them that Andrx had submitted an Abbreviated New Drug Application (“ANDA”) to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use and sell diltiazem HCL extended release tablets, 420 mg as a generic version of CARDIZEM<sup>®</sup> LA 420 mg tablets and that it sought approval of its ANDA prior to the expiration of the ’791 patent. Andrx denies that

there is information sufficient to form a belief as to the remaining allegations contained in paragraph 15 of the Complaint.

16. Andrx admits that the product that is the subject of its ANDA No. 77-686 will contain beads that will be compressed with other excipients into tablets. Andrx denies the remaining allegations contained in paragraph 16 of the Complaint.

17. To the extent that Paragraph 17 of the Complaint states conclusions of law, Andrx states that no response is required. Andrx denies the allegations contained in paragraph 17 of the Complaint because Andrx does not infringe any valid and enforceable claim of the '791 patent.

18. To the extent that Paragraph 18 of the Complaint states conclusions of law, Andrx states that no response is required. Andrx denies the allegations contained in paragraph 18 of the Complaint.

19. Andrx denies each and every other allegation of the Complaint not expressly admitted above.

#### **FIRST AFFIRMATIVE DEFENSE**

20. Upon information and belief, Andrx has not infringed any valid and enforceable claim of United States Patent No. 5,529,791 (the '791 patent).

#### **SECOND AFFIRMATIVE DEFENSE**

21. Upon information and belief, Andrx alleges that the '791 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §102.

#### **THIRD AFFIRMATIVE DEFENSE**

22. Upon information and belief, Andrx alleges that the '791 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §103.

**FOURTH AFFIRMATIVE DEFENSE**

23. Upon information and belief, Andrx alleges that the '791 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §112.

**FIFTH AFFIRMATIVE DEFENSE**

24. Upon information and belief, Andrx alleges that Biovail is precluded from alleging infringement by virtue of the doctrines of res judicata and collateral estoppel, in light of *Biovail Corp. Intern. v. Andrx Pharmaceuticals, Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000), *aff'd* 239 F.3d 1297 (Fed.Cir. 2001).

**COUNTERCLAIMS FOR DECLARATORY JUDGMENT**

Andrx counterclaims against Plaintiff, Biovail Laboratories International SRL, for declaratory relief and alleges:

25. Subject matter jurisdiction for this counterclaim for declaratory judgment is based upon 28 U.S.C. §§ 1338, 2201, and 2202 and Rule 13 of the Federal Rules of Civil Procedure. An actual case or controversy exists between Biovail and Andrx based upon Biovail having filed this complaint against Andrx.

**COUNT I**

26. Andrx incorporates by reference and re-alleges the allegations in paragraphs 20-25 of this Answer.

27. Andrx is entitled to a judgment declaring that it has not infringed any valid and enforceable claim of the '791 patent.

**COUNT II**

28. Andrx incorporates by reference and re-alleges the allegations in paragraphs 20-25 of this Answer.

29. Andrx is entitled to a judgment declaring that the '791 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §102.

**COUNT III**

30. Andrx incorporates by reference and re-alleges the allegations in paragraphs 20-25 of this Answer.

31. Andrx is entitled to a judgment declaring that the '791 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §103.

**COUNT IV**

32. Andrx incorporates by reference and re-alleges the allegations in paragraphs 20-25 of this Answer.

33. Andrx is entitled to a judgment declaring that the '791 patent is invalid for failure to comply with one or more of the requirements for patentability in 35 U.S.C. §112.

**COUNT V**

34. Andrx incorporates by reference and re-alleges the allegations in paragraphs 20-25 of this Answer.

35. Andrx is entitled to a judgment declaring that Biovail is precluded from asserting infringement of the '791 patent based on Andrx's ANDA No. 77-686, in light of *Biovail Corp. Intern. v. Andrx Pharm., Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000), *aff'd* 239 F.3d 1297 (Fed.Cir. 2001).

**WHEREFORE**, Andrx demands:

A. That the Complaint filed herein be dismissed and that the Plaintiff have and recover nothing by reason thereof;

B. that United States Patent No. 5,529,791 be declared and adjudged invalid;

- C. that United States Patent No. 5,529,791 be declared and adjudged unenforceable;
- D. that it be declared and adjudged that Andrx has not infringed and will not infringe any valid and enforceable claim of United States Patent No. 5,529,791;
- E. that this case be adjudged and decreed an exceptional case under 35 U.S.C. § 285 and that Andrx be entitled to recover reasonable attorneys' fees and costs incurred in this action;
- F. that Andrx be awarded damages, including punitive damages, for the assertion of a patent which Counterclaim Defendant knew to be invalid and/or unenforceable;
- G. such other and further relief as the Court deems just and equitable.

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**CERTIFICATE OF SERVICE**

I, William J. Cattie, III, Esq., do hereby certify that on September 26, 2005, I have E-filed through LEXIS NEXIS the **ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** following individual(s):

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